

AMENDMENTS TO THE SPECIFICATION

Replace paragraphs [0001], [0003], [0026], [0068], [0094], [0097], [0110] and [0127] with the following:

[0001] This application is related to copending U.S. Patent Application Serial No. [[] 10/765,625, filed January 26, 2004, entitled "Augmenting Hypoventilation" (Attorney Docket No. A04P1009), filed concurrently herewith, and which is incorporated by reference herein.

[0003] Central apnea and hypopnea stem from insufficient central nervous system drive and result in inadequate ventilation. Many of those afflicted also suffer from congestive heart failure (CHF). A particular form of apnea and hypopnea is known as Cheyne-Stokes Respiration (CSR), in which tidal volume oscillates between hyperpnea and hypopnea and/or apnea with a periodicity on the order of about 70 seconds. In general, CSR occurs during sleep and therefore CSR can preclude quality sleep through induction of apnea-terminating arousals. CSR also burdens the heart with transient episodes of hypoxia and surges in sympathetic tone, which can exacerbate CHF.

[0026] Fig. 1 shows an exemplary stimulation device 100 in electrical communication with a patient's heart 102 by way of three leads 104, 106, 108, suitable for delivering multi-chamber stimulation and shock therapy. The leads 104, 106, 108 are optionally configurable for delivery of stimulation pulses suitable for stimulation of nerves (e.g., autonomic nerves, phrenic nerves, etc.) and/or muscle tissue other than myocardial tissue. In addition, the device 100 includes a fourth lead 110 having, in this implementation, three electrodes 144, 144', 144'' suitable for stimulation of nerves (e.g., autonomic nerves, phrenic nerves, etc.) and/or muscle and/or detection of other physiologic signals that may be used by the implanted system to modify stimulation parameters. The lead 110 may be positioned in and/or near a patient's heart, near a nerve (e.g., an autonomic nerve, a phrenic nerve, etc.) or near muscle tissue other than myocardial tissue within a patient's body and remote from the heart. The right atrial lead 104, as the name implies, is positioned in and/or passes through a patient's right

atrium. The right atrial lead 104 optionally senses atrial cardiac signals and/or provide provides right atrial chamber stimulation therapy. As shown in Fig. 1, the stimulation device 100 is coupled to an implantable right atrial lead 104 having, for example, an atrial tip electrode 120, which typically is implanted in the patient's right atrial appendage. The lead 104, as shown in Fig. 1, also includes an atrial ring electrode 121. Of course, the lead 104 may have other electrodes as well. For example, the right atrial lead optionally includes a distal bifurcation having electrodes suitable for stimulation of nerves and/or muscle tissue.

[0068] Transvenous phrenic nerve stimulation involves positioning one or more ~~electrode or pole~~ electrodes or poles in a vessel proximate to a phrenic nerve. For example, the right phrenic nerve runs along the intimal tissue of the superior vena cava and the left phrenic nerve runs near the innominate vein. In general, stimulation energy and power for transvenous stimulation exceeds that of direct phrenic nerve stimulation. The diaphragm is segmented into approximately two hemidiaphragms; thus, stimulation of a right phrenic nerve may act to activate primarily the right hemidiaphragm while stimulation of a left phrenic nerve may act to activate primarily the left hemidiaphragm. Various studies indicate that an adequate level of respiration may be achieved via activation of a single hemidiaphragm. As described herein, diaphragm activation may involve right and/or left hemidiaphragm activation.

[0094] With respect to calling for artificial diaphragm activation in response to oscillations or a decrescendo and/or crescendo characteristic of CSR, Fig. 9 shows an exemplary method 900 that aims to terminate such oscillations or decrescendo or crescendo. The exemplary method 900 may be implemented after detection of oscillations characteristic of CSR.

[0097] As already mentioned, various exemplary mechanisms (e.g., suitably implemented as or in methods, devices, systems, etc.) aim to treat issues associated with Cheyne-Stokes respiration (CSR). CSR is typically characterized by alternating periods of hyponea hypopnea or apnea and hyperpnea wherein, for example, over a period of about 1 minute, an episode of about 10 to about 20 seconds of apnea or

hypopnea may be observed followed by respirations of increasing depth and perhaps frequency. While frequency information may be used, an exemplary mechanism may rely predominantly on an amplitude measure. Further, CSR often repeats, thus, there may be a characteristic repetition cycle associated with CSR. Knowledge of repetition may be gained through sensing and/or other means (e.g., patient monitoring, follow-up, etc.) and may be used in determining when to call for artificial diaphragm activation.

[0110] Fig. 13 shows an exemplary scenario 1300 wherein augmentation of respiration occurs. The scenario 1300 includes a plot 1310 of exemplary data, for example, sensed via a [[senor]] sensor or monitor. An expiratory limit 1312 and an inspiratory limit 1312' indicate circumstances or conditions where artificial diaphragm activation may aid breathing. According to the scenario 1300, event 1 corresponds to sensing of indicia that indicate an adequate level of upper airway patency. The corresponding expiratory phase of the cycle exhibits a maximum air flow that is less than the expiratory limit 1312 (event 2). In response to the indicia of an adequate level of upper airway patency and an expiratory air flow that is less than the expiratory limit 1312, stimulation for artificial diaphragm activation is delivered that commences at approximately the end of the expiratory phase (event 3).

[0127] Various exemplary methods, devices and/or systems optionally include one or more features described in the aforementioned co-pending application. For example, referring to the exemplary scenario 1100 of Fig. 11, another limit may exist above the limit [[1102]] 1112 wherein a different therapy is applied. Such a therapy may include calling for stimulation for diaphragm activation at an energy or power based on a difference between the actual tidal volume and the other limit or on the tidal volume or other respiration variable wherein energy or power may be based on a nonincreasing monotonic relationship with respect to increasing tidal volume; whereas, if tidal volume falls below the limit [[1102]] 1112, a change in therapy occurs whereby a call for stimulation may rely on a stimulation energy or power based on a nondecreasing monotonic relationship with respect to increasing tidal volume. Of course, a number of limits may be used that have one or more associated therapies such as those described herein, in the co-pending application and/or elsewhere. An exemplary method may

include sensing respiratory information related to tidal volume, based at least in part on the respiratory information, determining if tidal volume is between an upper limit and a lower limit and, if the tidal volume is between the upper limit and the lower limit, calling for diaphragm activation at a stimulation power based on a nonincreasing monotonic relationship with respect to increasing tidal volume or, if the tidal volume is less than the lower limit, calling for diaphragm activation at a stimulation power based on a nondecreasing monotonic relationship with respect to increasing tidal volume.